

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use In Animal Feeds; Bacitracin Methylene Disalicylate and Decoquinatate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for using approved bacitracin methylene disalicylate (BMD) and decoquinatate Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis, and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1600.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-102 that provides for combining approved BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) BMD), and Deccox® (6 percent decoquinatate) Type A medicated articles to make Type C medicated feeds for broiler chickens containing 4 to 50 grams per ton (g/t) BMD and 27.2 g/t decoquinatate. The Type C medicated broiler feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*, *E. acervulina*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of August 3, 1998, and the regulations in 21 CFR 558.76(d)(3) and the

table in 21 CFR 558.195(d) are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.76 is amended by adding paragraph (d)(3)(xviii) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

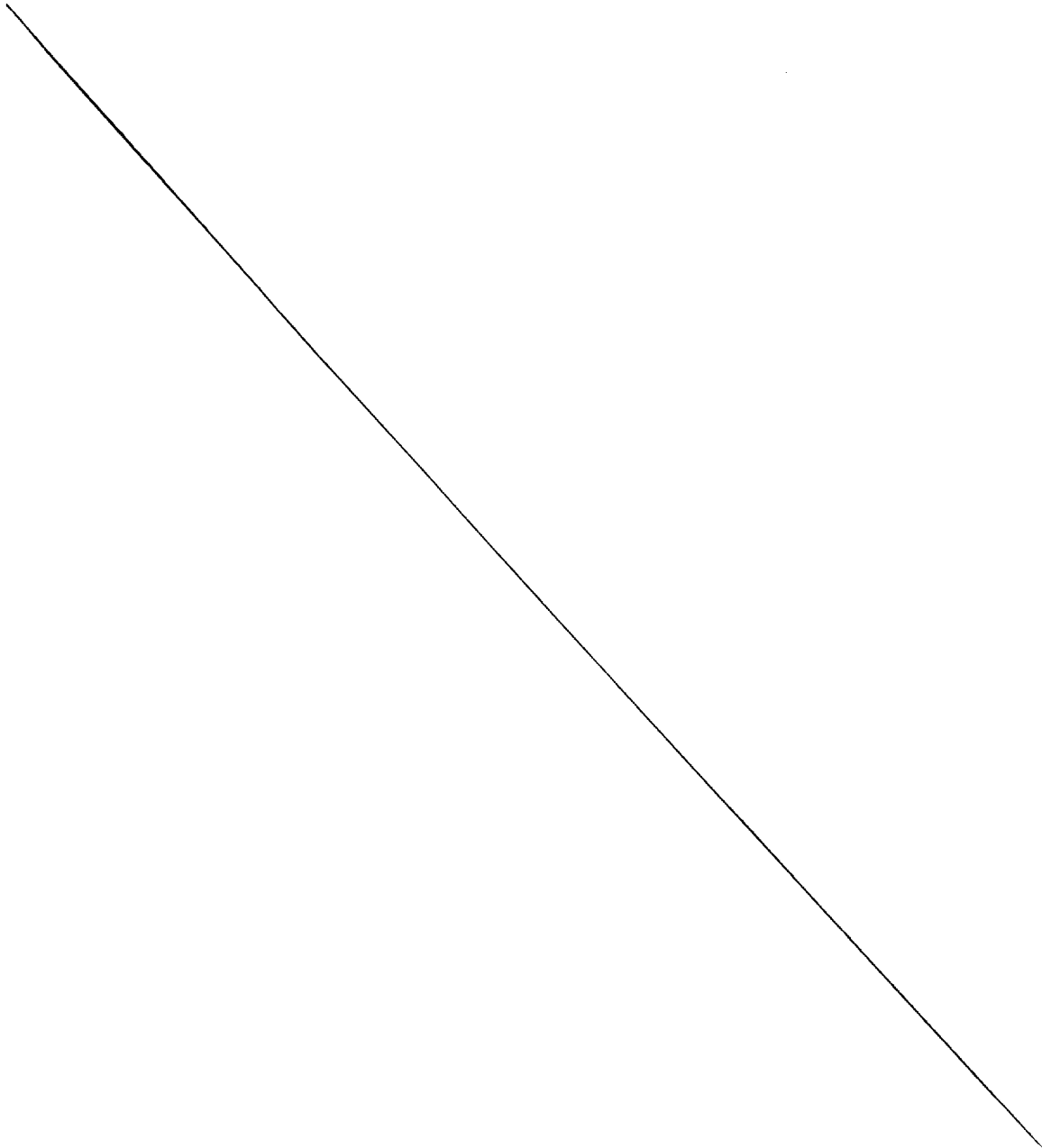
(3) * * *

(xviii) Decoquate as in § 558.195.

3. Section 558.195 is amended in the table in paragraph (d) by adding an entry under “27.2(0.003 pct)” before the entry for “Bacitracin 10 to 50” to read as follows:

§ 558.195 Decoquate.

* * * * *



(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* 27.2 (0.003 pct) *	* * Bacitracin 4 to 50 *	* * Broiler chickens; for the prevention of coc- cidiosis caused by <i>Eimeria tenella</i> , <i>E.</i> <i>necatrix</i> , <i>E. mivati</i> , <i>E. acervulina</i> , <i>E.</i> <i>maxima</i> , and <i>E. brunetti</i> , and for in- creased rate of weight gain and im- proved feed efficiency. *	* * Do not feed to laying chickens; feed con- tinuously as sole ration; bacitracin meth- ylene disalicylate as provided by 046573 in § 510.600(c) of this chapter. *	* * 046573 *

Dated: 8/27/98
 August 27, 1998

Stephen F. Sundlof
 Director
 Center for Veterinary Medicine

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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